

REMARKS

Claims 1 and 4-13 are pending after entry of this paper. Claims 1 and 4-13 have been rejected. Claims 2, 3, and 14-16 have been previously cancelled without prejudice. Applicants reserve the right to pursue cancelled claims or subject matter in a continuing application.

Claim 1 has been amended to replace the transitional phrase “comprising” with the transitional phrase “consisting essentially of.”

Claim 7 has been amended to replace the temperature range from “10 to 70°C” to “45 to 65°C.” Support may be found throughout the instant specification, for instance, see page 12 of the specification as filed.

Claim 13 has been amended to replace the phrase “separated into water and protein, in the isolation step” with the phrase “dried in the drying step.” Support may be found throughout the instant specification and claims, for instance, see claim 1, step (c).

No new matter has been introduced by these amendments. Reconsideration and withdrawal of the pending objections and rejections in view of the above claim amendments and below remarks are respectfully requested.

Response to Rejections under 35 U.S.C. § 112

Claim 13 has been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Specifically, the Examiner contends that the limitation “the isolation step” in line 3 of the claim does not allegedly have antecedent basis. Applicants respectfully disagree. However, in order to expedite prosecution and without disclaimer of, or prejudice to, applicants have amended claim 13 to delete the expression “separated into water and protein, in the isolation

step” and replace it with the expression “dried in the drying step.” Applicants believe that the Examiner’s concerns have been fully addressed and respectfully request reconsideration and withdrawal of the 35 U.S.C. § 112, second paragraph rejection for indefiniteness.

Response to Rejections under 35 U.S.C. § 103

Claims 1, 4-11, and 13 stand rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over U.S. Patent No. 6,630,195 to Muralidhara, et al. (“Muralidhara”) in view of Japanese Patent No. JP 44-6211 B to General Foods Corp. (“General Foods”) and U.S. Patent No. 3,653,912 to Koski, et al. (“Koski”). Specifically, the Examiner contends that Muralidhara anticipates each and every element of claims 1, 4-11, and 13 except that Muralidhara is admittedly silent as to the use of *acid washing* and to the starting protein content of the extraction process (Office Action - page 4). The Examiner contends that this deficiency of Muralidhara is remedied by General Foods, which allegedly discloses the method of acid washing protein flakes. Therefore, the Examiner contends that it would have been obvious to one of ordinary skill in the art at the time the invention was filed to achieve the allegedly predictable result of removing components other than soy protein as taught by General Foods, *i.e.*, acid washing, before subjecting the soy protein to the counter-current extraction process of Muralidhara. Applicants respectfully disagree with Examiner’s reasoning and conclusion.

Applicants assert that contrary to the Examiner’s contention, the claimed invention is not made obvious by the combination of Muralidhara, General Foods, and Koski. Applicants respectfully wish to draw the Examiner’s attention to MPEP 2141, which states that

[T]he mere fact that references can be combined or modified does not render the resultant combination obvious unless the results would have been predictable to one of ordinary skill in the art. *KSR*

International Co. v. Teleflex Inc., 550 U.S., 82 USPQ2d 1385, 1396 (2007) (emphasis added)

Muralidhara describes a method for isolating a soy protein by two essential steps: *i*) an extraction step; and *ii*) an isolation step using membrane filtration. The extraction step is carried out by a multi-stage counter current extraction process, where the protein is separated from defatted soybean with an aqueous medium at a neutral to alkaline pH, and the particulate material present in the extract suspension, such as water-insoluble cellulosic components, is removed prior to membrane filtration to produce a clarified extract. (*Id.* col. 8, ln. 9-19). The isolation step, on the other hand, allows the removal of “carbohydrates, salts and other non-protein components” (col. 5, lns. 36-44 and FIG. 5) from the clarified extract and the isolation of soy protein on a membrane. Applicants respectfully note that the purpose of membrane filtration in Muralidhara is to separate and concentrate protein (*e.g.*, globulin and albumin) from water-soluble carbohydrates, salts and other water-soluble components (*Id.* col. 5, ln. 45-47), similar to an acid-precipitation step. In fact, the U.S. Patent No. 3,586,662 to O'Connor (cited by the Examiner) at col. 5, ln. 28-32 notes that the “membrane filtration” step can be applied instead of acid precipitation during protein recovery.

General Foods, on the other hand, describes a method for isolating soy protein by three essential steps: *i*) an acid-washing step - removing the whey and carbohydrates; *ii*) an extraction step - extracting protein from the acid-washed soybean slurry; and *iii*) an isolation step using acid-precipitation - isolating the protein from the protein extract obtained by the extraction step (pg. 2, lns. 18-29). During the acid-washing step, the slurry is maintained at the desired pH and temperature for a sufficient time so that all the soluble substances comprising soluble proteins (albumin and albuminoid), soluble carbohydrates and soluble salts are solubilized. The soluble moiety obtained after the acid-washing step is separated from the insoluble moiety by a

common separation method, typically by filtration or centrifugation. “The unnecessary soluble moiety is discarded, and the insoluble moiety including insoluble proteins, cellulose components and insoluble salts is suspended ... to make a slurry.” (General Foods; page 2, left column, lines 13-30). Applicants respectfully assert that the purpose of acid washing in General Foods is to remove soluble materials consisting of acid-soluble proteins (*e.g.*, albumin), water-soluble carbohydrates and salts and not to separate and concentrate water-soluble proteins (*e.g.*, globulin and albumin).

Applicants respectfully assert that none of the cited references, *i.e.*, Muralidhara, General Foods, alone or in combination describe, teach or suggest the method for isolating soy-protein in high purity and yield by three essential steps: i) an acid-washing step, removing the whey and carbohydrates; ii) an extraction step by a counter-current extraction method; extracting protein from the acid-washed soybean slurry; and iii) sterilization and drying step; with an essential limitation that no acid precipitation occur after the extraction. In combining Muralidhara with General Foods, the Examiner contends that since “[b]oth the ‘195 patent [Muralidhara] and General Foods teach a method for removing components other than soy protein from the processing stream (the ‘195 patent by filtration, General Foods by acid washing) it would have been obvious to one of ordinary skill in the art to achieve the predictable result of removing components other than soy protein by acid washing as taught by General Foods before subjecting the soy protein to the counter-current extraction process of the ‘195 patent.” Applicants respectfully disagree.

Assuming for argument sake that a skilled artisan could combine the acid-washing step of General Foods with the soy-protein isolation method of Muralidhara. Nonetheless, a skilled artisan would still not arrive at the claimed invention. As noted above, the

purpose of acid washing in General Foods is to remove soluble materials consisting of acid-soluble proteins (*e.g.*, albumin), water-soluble carbohydrates and salts, whereas the purpose of membrane filtration in Muralidhara is to separate and concentrate protein (*e.g.*, globulin and albumin) from water-soluble carbohydrates, salts and other water-soluble components (*Id.* col. 5, ln. 45-47), similar to an acid-precipitation step. In essence, these are two competing techniques and are not compatible. In other words, if the method has an acid-washing step, then a skilled artisan would not and could not introduce a filtration step because the components that the filtration step was designed to separate and concentrate would not be part of the slurry anymore. On the other hand, if the method has a filtration, then a skilled artisan would not and could not introduce an acid-washing step because it would interfere with the filtration step. Thus, contrary to the Examiner's conclusion, the mere fact that the filtration step of Muralidhara and the acid-washing step of General Foods help to isolate soy-protein from the defatted soy flakes does not make these two method steps compatible and readily interchangeable. In fact, adding the acid-washing step as proposed by the Examiner, will substantially change the invention of Muralidhara and would make it inoperable because the acid-washing step will eliminate the soluble components of the slurry that are separated and concentrated by the filtration step of Muralidhara. MPEP 2143.01 clearly states that the proposed modification of the prior art cannot change the principle of operation of the primary reference or render the reference inoperable for its intended purpose. Muralidhara and General Foods generate/produce/obtain substantially different soy protein compositions. For instance, Muralidhara separates a protein, in which water-soluble albumin is mixed and present other than the alkali-soluble and acid-insoluble globulin. Whereas, General Foods separates and concentrates protein consisting of the albumin-free globulin. Applicants respectfully assert that the acid-washing step would render the method

disclosed in Muralidhara inoperable (*i.e.*, would interfere with the filtration step) and unsatisfactory for its intended purpose (*i.e.*, different product attained). A skilled artisan would have no suggestion or motivation to make the Examiner's proposed modification without completely modifying the method disclosed in the primary reference, and, therefore, can not be used as a basis for a rejection. (See MPEP 2143.01).

Furthermore, applicants respectfully wish to draw the Examiner's attention to MPEP 2141 once more, which states that

[I]n determining the differences between the prior art and the claims, the question under 35 U.S.C. 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983); *Schenck v. Nortron Corp.*, 713 F.2d 782, 218 USPQ 698 (Fed. Cir. 1983). (emphasis added)

A prior art reference must be considered in its entirety, *i.e.*, as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984). (emphasis added)

General Foods employs the acid-washing step in conjunction with the acid-precipitation step. As shown in the comparative study performed by the applicants (see Declaration under 1.132 by Hiroyuki Kato), the quality of the isolated soy-protein product by General Foods method degrades. In fact, such product has an irritating sense and astringency, which makes it unsatisfactory for its intended use in food. (see page 5 of the declaration). However, assuming for argument sake, that the acid-precipitation step of General Foods can be eliminated. Yet, the outcome is that the protein yield and purity deteriorate below the desired purity level. (see pages 6-8 of the declaration). In other words, General Foods teaches as confirmed by the comparative study that the acid-washing step must be performed together with

the acid-precipitation step in order to maintain the satisfactory soy-protein yield and purity.

Therefore, since the claimed method explicitly requires that the soy-protein isolation process to be performed without the acid-precipitation step, the disclosure of General Foods teaches away from the claimed invention.

Furthermore, a skilled artisan, upon reading the disclosures of Muralidhara and General Foods, would not have sufficient guidance to modify the methods of Muralidhara and General Foods to result in the method as claimed by looking at Koski. Specifically, Koski relates to an invention for improving solubility and flavor of soy material (especially soymilk powder) and for producing a soy beverage. The means to improve soy material is a method in which soy material is dissolved in water and then made to be strong-alkaline by adjusting the pH to 12, which is then neutralized to pH 7. The soy protein is then used directly from solution, or may be spray-dried. Applicants respectfully assert that Koski does not compensate for the shortcomings of Muralidhara and General Foods, nor would it be obvious to combine Muralidhara and General Foods with Koski.

Koski discloses a purification of a protein to no more than about 30 to 70%, and only 43.6% in the Examples where soymilk is used. Soy material of such purity cannot be regarded as the "isolated soy protein," and, in fact, high purity is undesirable according to Koski “[s]oy materials having a larger protein content, however, may be used with less preferred results.” (col. 2; lns. 13-15), which in essence teaches away from the claimed invention. Even when a highly purified soy protein is used, according to Koski such purity is achieved by an acid-precipitation step (col. 1, ln. 73 to col. 2, ln. 9), which again affectively leads away from the claimed invention. Therefore, applicants assert that Muralidhara and General Foods in view of Koski does not render obvious the claimed invention because the cited references do not

disclose, nor enable, a method which includes an acid-washing step and a counter-current extraction step, where an isolated soy protein with a high degree of purity is ultimately obtained by directly drying the extract from the soy protein extract solution, without conducting any purification step such as acid-precipitation or membrane filtration as disclosed in General Foods, Koski and Muralidhara. Thus, the claimed method is not obvious in view of the combined disclosure of Muralidhara, General Foods and Koski.

Applicants respectfully assert that Muralidhara, General Foods and Koski, either alone or in combination, does not teach each and every element of the claimed invention and, in fact, leads away one skilled in the art from the claimed invention. Therefore, for at least the reason stipulated above, applicants assert that the cited references do not make obvious the claimed invention. Applicants respectfully request reconsideration and withdrawal of the 35 U.S.C. §103(a) rejection of claims 1, 4-11, and 13.

Claims 1, 4-11 and 13 are rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over U.S. Patent No. 6,630,195 to Muralidhara, et al. (“Muralidhara”) in view of U.S. Patent No. 3,586,662 to O’Connor (“O’Connor”) and U.S. Patent No. 3,653,912 to Koski, et al. (“Koski”). Specifically, the Examiner contends that Muralidhara anticipates each and every element of claims 1, 4-11, and 13 except that Muralidhara is admittedly silent as to the use of *acid washing* and to the starting protein content of the extraction process (Office Action - page 7). The Examiner contends that this deficiency of Muralidhara is remedied by O’Connor, which allegedly discloses the method of acid washing protein flakes. Therefore, the Examiner contends that it would have been obvious to one of ordinary skill in the art at the time the invention was

filed to achieve the allegedly predictable result of removing components other than soy protein as taught by O'Connor, *i.e.*, acid washing, before subjecting the soy protein to the counter-current extraction process of Muralidhara. Applicants respectfully disagree with Examiner's reasoning and conclusion.

O'Connor discloses a method for isolating protein from sunflower meal.

O'Connor describes a method for isolating sunflower protein by three essential steps: *i*) an acid-washing step; *ii*) an alkaline extraction step; and *iii*) an acid-precipitation step to obtain the protein extract solution. O'Connor also describes, as mentioned above, that "membrane filtration" can be applied instead of acid precipitation. (col. 5, lns. 28-32). In essence, the O'Connor method teaches nothing more than the General Foods method and, just like General Foods method, requires a subsequent acid precipitation step after the initial acid washing step because protein cannot be purified to a high purity only by acid washing as previously discussed and presented in the comparative study. (see Declaration under 1.132 by Hiroyuki Kato). Therefore, since the claimed method explicitly requires that the soy-protein isolation process is performed without the acid-precipitation step, the disclosure of O'Connor teaches away from the claimed invention.

Moreover, adding the acid-washing step as proposed by the Examiner, will substantially change the invention of Muralidhara and would make it inoperable because the acid-washing step will eliminate the soluble components of the slurry that are separated and concentrated by the filtration step of Muralidhara. MPEP 2143.01 clearly states that the proposed modification of the prior art cannot change the principle of operation of the primary reference or render the reference inoperable for its intended purpose. Muralidhara and O'Connor generate/produce/obtain substantially different protein compositions. Applicants respectfully

assert that the acid-washing step would render the method disclosed in Muralidhara inoperable (*i.e.*, would interfere with the filtration step) and unsatisfactory for its intended purpose (*i.e.*, different product attained). A skilled artisan would have no suggestion or motivation to make the Examiner's proposed modification without completely modifying the method disclosed in the primary reference, and, therefore, can not be used as a basis for a rejection. (See MPEP 2143.01).

Applicants respectfully assert that Muralidhara, in view of O'Connor and Koski, either alone or in combination, does not teach each and every element of the claimed invention and, in fact, leads away one skilled in the art from the claimed invention. Therefore, for at least the reason stipulated above, applicants assert that the cited references do not make obvious the claimed invention. Applicants respectfully request reconsideration and withdrawal of the 35 U.S.C. §103(a) rejection of claims 1, 4-11, and 13.

Claim 12 is rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over U.S. Patent No. 6,630,195 to Muralidhara, et al. ("Muralidhara") in view of U.S. Patent No. 3,586,662 to O'Connor ("O'Connor"), U.S. Patent No. 3,653,912 to Koski, et al. ("Koski"), and U.S. Patent No. 4,186,218 to Gomi ("Gomi").

Specifically, the Examiner contends that Muralidhara anticipates each and every element of claim 12 as it depends from claim 1, except that Muralidhara, O'Connor, and Koski are admittedly silent as to the use of an emulsifier in the acid washing step. The Examiner contends that this deficiency of Muralidhara, O'Connor and Koski is remedied by Gomi, which allegedly discloses the use of an emulsifier including glycerin fatty acid esters, for example, for the processing of soybean flake material. Applicants respectfully disagree.

However, applicants believe that the arguments submitted with respect to the §103(a) obviousness rejection over Muralidhara in view of O'Connor and Koski (see above) are sufficient to overcome the §103(a) obviousness rejection over Muralidhara in view of O'Connor and Koski in further view of Gomi. For example, Gomi does not disclose or suggest isolating a soy protein with an acid-washing step but without the acid-precipitation step as required by the claims as presently pending. Since the disclosure of Gomi does not remedy the deficiencies of Muralidhara, O'Connor and Koski, Gomi, either alone or in combination with Muralidhara, O'Connor and Koski, does not render obvious instant claim 12.

In view of the above amendments and arguments, applicants submit that the claims as presented herein are allowable over the art of record. Applicants respectfully request reconsideration and withdrawal of the 35 U.S.C. §103(a) obviousness rejection of claim 12.

Dependent Claims

The applicants have not independently addressed all of the rejections of the dependent claims. The applicants submit that for at least similar reasons as to why independent claim 1 from which all of the dependent claims 4-13 depend are believed allowable as discussed *supra*, the dependent claims are also allowable. The applicants however, reserve the right to address any individual rejections of the dependent claims and present independent bases for allowance for the dependent claims should such be necessary or appropriate.

Thus, applicants respectfully submit that the invention as recited in the claims as presented herein is allowable over the art of record, and respectfully request that the respective rejections be withdrawn.

CONCLUSION

Based on the foregoing amendments and remarks, applicants respectfully request reconsideration and withdrawal of the pending rejections and allowance of this application. The applicants respectfully submit that the instant application is in condition for allowance. In the event that a telephone conference would facilitate examination of this application in any way, the Examiner is invited to contact the undersigned at the number provided. Favorable action by the Examiner is earnestly solicited.

AUTHORIZATION

The Commissioner is hereby authorized to charge any additional fees which may be required for consideration of this Amendment to Deposit Account No. **50-4827**, Order No. 1700000-00010.

In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. **50-4827**, Order No. 1700000-00010.

Respectfully submitted,
Locke Lord Bissell & Liddell LLP

Dated: February 17, 2009

By:



Serge Ilin-Schneider, Ph.D.
Registration No. 61,584

Correspondence Address:

Locke Lord Bissell & Liddell LLP
3 World Financial Center
New York, NY 10281-2101

(212) 415-8600 Telephone
(212) 303-2754 Facsimile